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PATENT
Attorney Docket No. 56297-5010-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Martin J. GOLDBERG *et al.*

Application No.: 09/776,770

Filed: February 6, 2001

For: METHODS AND COMPOSITIONS FOR AMPLIFYING DETECTABLE SIGNALS IN SPECIFIC BINDING ASSAYS

Group Art Unit: 1634

Examiner: J. T. Cleveland

Commissioner for Patents
Washington, DC 20231

Sir:

RESPONSE TO OFFICE ACTION

The Office Action mailed April 11, 2002 has been carefully reviewed and the following remarks are made in response thereto. A two-month Extension of Time has been timely petitioned for and the fee therefore has been paid herewith. Accordingly, the period for response now expires on September 11, 2002. In view of the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

I. Summary of the Office Action

1. The Office Action rejected claims 1-27 under 35 U.S.C. §112, 2nd paragraph for allegedly using the term "amplification reagent" in a manner inconsistent with its art-accepted meaning.

2. The Office Action rejected claims 1-27 under 35 U.S.C. §101 for allegedly claiming the same invention as prior U.S. Patent 6,203,989.

II. Response to the Office Action

Rejection of claims 1-27 under 35 U.S.C. §112, 2nd paragraph

The Office Action alleges that the use of the term "amplification reagent" in the claims is repugnant to the usual meaning of the term in the art. The Office Action alleges that the term

> "is used by the claim to mean an antibody, or DNA matrix, or another element which will bind the reagent, while the accepted meaning is 'a reagent that aids in the amplification of nucleic acids' such as a buffer, magnesium, etc."

Applicants respectfully disagree with the ground of rejection and submit that the rejection is due to an interpretation of the claims not made in light of the specification. It is respectfully submitted that the meaning ascribed to the term "amplification reagent" as "the accepted meaning" by the Office Action is not the sole use of the term as accepted in the art. The term "amplification reagent" refers to any reagent which facilitates the increase of a particular process or product.

In the instant specification, the term "amplification reagent" is used to describe a reagent which amplifies a signal for the detection of the hybridization of a probe to a target molecule. For example, at lines 7-32 on page 3 of the instant specification, it is disclosed that methods are provided for detecting a nucleic acid target comprising hybridizing a target nucleic acid sequence comprising a binding ligand to a probe nucleic acid sequence. The target (comprising a binding ligand) is contacted with a receptor which binds to the binding ligand. The receptor is, in turn, contacted with an amplification reagent which comprises a plurality of the binding ligands. The presence of the complexed amplification reagent is then detected, for example, either by detecting the presence of a detectable label on at least one of the receptor or amplification reagent or by contacting the complexed amplification reagent with further labeled receptor molecules which bind to the plurality of binding ligands. Therefore, the "amplification reagent" of the instantly claimed invention clearly functions to amplify the signal of the original hybridization of the target nucleic acid sequence to the probe nucleic acid sequence, thereby facilitating detection of the complex. Accordingly, as used herein, the term "amplification reagent" is used in a manner consistent with an art accepted meaning to denote a reagent which "permits the detectable signal to be enhanced and more easily detectable" (page 3, lines 23-24,

for example). Accordingly, Applicants respectfully request withdrawal of the ground of rejection.

Rejection of claims 1-27 under 35 U.S.C. §101 for claiming the same invention as claims 1-27 of U.S. Patent 6,203,989

The Office Action alleges that the claims are drawn to the same invention as claims 1-27 of the '989 patent and therefore are subject to the double patenting provisions of 35 U.S.C. § 101. Applicants respectfully disagree with this position. In order for a claimed invention to be considered "the same" as another claimed invention and be subject to a statutory double patenting rejection, the claimed inventions must be identical. This is not the case in regard to the instantly claimed invention *versus* the invention claimed in the '989 patent. The instant claims require the presence of an "amplification reagent" in each of the base claims 1 (step c) and 23 (step d). In contrast, none of the claims of the '989 patent recite an "amplification reagent" as a limitation. Therefore, the claims are not drawn to the same invention, as the statute requires, and the rejection is improper. Accordingly, Applicants respectfully request withdrawal of the ground of rejection.

Conclusion.

In view of the foregoing remarks, the Applicants respectfully request withdrawal of all outstanding rejections and early notice of allowance to that effect. If the Examiner believes that allowance of this application may be expedited by a telephonic interview, she is encouraged to contact the undersigned.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

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August 21, 2002

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